IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF NEW YORK

MARCIA SABOL,

Plaintiff,

vs.

BAYER HEALTHCARE PHARMACEUTICALS INC.; BAYER CORPORATION; BAYER HEALTHCARE LLC; BRACCO DIAGNOSTICS, INC.; GE HEALTHCARE INC.; GENERAL ELECTRIC COMPANY; and McKESSON CORPORATION,

Defendants.

PLAINTIFF'S COMPLAINT FOR DAMAGES

COMES NOW Plaintiff, MARCIA SABOL, by and through undersigned counsel, and alleges as follows:

1. Gadolinium is a highly toxic heavy metal and rare earth element. It does not occur naturally in the human body. The only known route for gadolinium to enter the human body is by injection of a gadolinium-based contrast agent.

2. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, advertising, distribution, labeling, and/or sale of the pharmaceutical drugs Magnevist, MultiHance, and Omniscan, linear gadolinium-based contrast agents used in MRIs.

3. Plaintiff maintains that Magnevist, MultiHance, and Omniscan are defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lack proper warnings and directions as to the dangers associated with their use.

4. The gadolinium from Magnevist, MultiHance, and Omniscan did not leave the Plaintiff's body as promised, and instead it was retained permanently in multiple organs (brain,

heart, liver, kidney, bones, and skin). This gadolinium, a toxic heavy metal, caused fibrosis in Plaintiff's organs, bone, and skin, and crosses the blood-brain barrier and deposits in the neuronal nuclei of the brain.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because Defendants are all incorporated and have their principal places of business outside of the state in which the Plaintiff resides.

6. There is complete diversity of citizenship between Plaintiff and Defendants. Plaintiff is a resident and citizen of and is domiciled in the state of Florida. Plaintiff was a resident of New York for many of the events at issue in this Complaint.

7. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

8. This Court has personal jurisdiction over Defendants, each of which is licensed to conduct and is systematically and continuously conducting business in this state, including, but not limited to, the marketing, researching, testing, advertising, selling, and distributing of drugs, including Magnevist, MultiHance, and Omniscan, to the residents of this state.

9. The Bayer Defendants, at all relevant times, have and had significant contacts with the State of New York. The Bayer Defendants are all registered to do business in the State of New York with the New York Secretary of State. The Bayer Defendants operated at facility in Tarrytown, New York. The Bayer Defendants conducted clinical trials and other research regarding Magnevist in the State of New York. The Bayer Defendants sold the Magnevist that was administered to Plaintiff in the State of New York. Plaintiff received the injection of Defendant's Magnevist in the State of New York.

10. Defendant General Electric Company is a New York company with its principle place of business in Massachusetts. Defendant General Electric Company engaged in the manufacturing, testing, licensing, design, marketing, selling, distributing, and advertising of Omniscan in the State of New York.

11. Defendant McKesson Corporation at all relevant times, has and had significant contacts with the State of New York. Defendant McKesson Corporation is registered to do business in the State of New York with the New York Secretary of State. Defendant McKesson Corporation distributed and sold the Magnevist and MultiHance that was administered to Plaintiff in the State of New York. Plaintiff received the injections of the Magnevist in the State of New York.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the Defendants conduct business in New York and are subject to personal jurisdiction in this District. Defendants sell, advertise, market and/or distribute Magnevist, MultiHance, and Omniscan within the Southern District of New York, and do substantial business in this state and within this District.

13. Defendants developed, manufactured, promoted, marketed, tested, researched, distributed, warranted, and sold Magnevist, MultiHance, and Omniscan in interstate commerce.

PARTIES

14. At many times relevant to this complaint, Plaintiff was a resident of the Southern District of New York.

15. Plaintiff has had approximately six MRIs in the State of New York. Before each, she was injected with linear gadolinium-based contrast agents in the State of New York. Plaintiff has had approximately four MRIs in the State of Florida. Before each, she was injected with linear gadolinium-based contrast agents.

16. Plaintiff MARCIA SABOL was injected with the linear gadolinium-based contrast agents ("GBCAs") Magnevist, MultiHance, and Omniscan prior to receiving MRIs. Unbeknownst to her and contrary to the Defendant's promotion of GBCAs as being benign contrast agents that harmlessly exit the body shortly after administration in patients who did not have chronic/severe kidney disease or acute kidney injury, Ms. Sabol continues to have retained gadolinium in her body, many years after being administered the GBCA.

17. Plaintiff's primary injury alleged herein is gadolinium retention in multiple

organs (brain, heart, liver, kidney, bones, and skin). The gadolinium, a toxic heavy metal, caused fibrosis in organs, bone, and skin, and crossed the blood-brain barrier and deposited in the neuronal nuclei of the brain.

18. Plaintiff was never warned about the risks of gadolinium retention because she did not have chronic/severe kidney disease or acute kidney injury, and the GBCA manufacturers chose to only provide warnings to patients with these types of reduced renal function.

19. Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, and Bayer Healthcare LLC (collectively referred to as the "Bayer Defendants') manufacture, market, and sell Magnevist, a gadolinium-based contrast agent that was injected into Plaintiff's body.

20. Defendant Bayer Healthcare Pharmaceuticals Inc. is a Delaware corporation with its principal place of business in New Jersey, where its headquarters are located and from where its officers direct, control, and coordinate the company's activities. Bayer Healthcare Pharmaceuticals Inc. is thus a citizen of both the State of Delaware and the State of New Jersey. Defendant Bayer Healthcare Pharmaceuticals Inc. is the United States pharmaceuticals unit of Bayer Healthcare LLC. Bayer Healthcare Pharmaceuticals Inc. is engaged in the business of testing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

21. Bayer Corporation is the sole member of Bayer Healthcare LLC. Bayer Corporation is incorporated under the laws of the State of Indiana with its principal place of business in Pennsylvania, where its headquarters are located and from where its officers direct, control, and coordinate the company's activities. Bayer Corporation is thus a citizen of both the State of Indiana and Commonwealth of Pennsylvania. Defendant Bayer Corporation is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties

or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

22. Bayer HealthCare LLC is engaged in the business of testing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Magnevist into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

23. Defendant Bayer Healthcare LLC is a Delaware Corporation with its principal place of business in New Jersey. Bayer Healthcare LLC is registered to do business in New York, but no member or owner of Bayer Healthcare LLC is domiciled in Florida. The officers of Bayer Healthcare LLC reside in Pennsylvania, New Jersey, Kansas, and California.

24. In a Corporate Disclosure Statement, Bayer Healthcare LLC certified that: "Bayer HealthCare LLC is a nongovernmental entity. Bayer HealthCare LLC is a Delaware limited liability company whose members are NippoNex Inc., Bayer Medical Care Inc., Bayer West Coast Corporation, Bayer Essure, Inc., Bayer Consumer Care Holdings LLC, Dr. Scholl's LLC, Coppertone LLC, MiraLAX LLC, and Bayer HealthCare US Funding LLC, and as such Bayer HealthCare LLC is owned by those entities." *Mansolillo v. Bayer, et al*, United States District Court Northern District of California; Case No. 3:18-cv-6015; Doc. 8; Filed 10/01/18. Therefore, Bayer Healthcare LLC certifies that it has nine (9) members/owners. *Id*.

25. The first member/owner of Bayer Healthcare LLC is "NippoNex Inc." *Id*. NippoNex Inc. is a Delaware corporation. *Id*. NippoNex Inc.'s principal place of business is in New Jersey.

26. The second member/owner of Bayer Healthcare LLC is "Bayer Medical Care Inc." *Id*. Bayer Medical Care Inc. is a Delaware corporation. *Id*. Bayer Medical Care Inc.'s

principal place of business is in Pennsylvania.

27. The third member/owner of Bayer Healthcare LLC is "Bayer West Coast Corporation." *Id*. Bayer West Coast Corporation is a Delaware corporation. *Id*. Bayer West Coast Corporation's principal place of business is in California.

28. The fourth member/owner of Bayer Healthcare LLC is "Bayer Essure, Inc." *Id*. Bayer Essure, Inc. is a Delaware corporation. *Id*. Bayer Essure, Inc.'s principal place of business is in New Jersey..

29. The fifth member/owner of Bayer Healthcare LLC is "Bayer Consumer Care Holdings LLC." *Id*. Bayer Consumer Care Holdings LLC's principal place of business is in New Jersey. Bayer Consumer Care Holdings LLC is a Delaware limited liability company whose sole common member is Bayer East Coast LLC, and whose sole preferred member is Bayer HealthCare US Funding LLC. *Id*.

30. Bayer East Coast LLC is a Delaware limited liability company, whose sole member is Bayer US Holding LP, and as such, is wholly-owned by Bayer US Holding LP. *Id*. Bayer US Holding LP is a Delaware limited partnership.

31. Bayer HealthCare US Funding LLC is a Delaware limited liability company whose members are Bayer AG, Bayer Pharmaceuticals AG, and Bayer World Investments B.V. *Id*. Bayer AG is a German corporation. *Id*. Bayer Pharmaceuticals AG is a German corporation. *Id*. Bayer World Investments B.V. is a private company with limited liability incorporated under the laws of the Netherlands and is wholly-owned by Bayer AG. *Id*.

32. Bayer US Holding LP is a limited partnership incorporated in Delaware. Bayer US Holding LP's General Partner is Bayer World Investments B.V., which has a corporate address of Energieweg 13641 RT Mijdrecht, Netherlands. Bayer US Holding LP is therefore a citizen of the Netherlands, Europe.

33. The sixth member/owner of Bayer Healthcare LLC is "Dr. Scholl's LLC." *Id*. Dr. Scholl's LLC's principal place of business is in California. Dr. Scholl's LLC is a Delaware limited liability company. *Id*. The sole member/owner of Dr. Scholl's LLC is Bayer HealthCare

US Funding LLC. *Id.* Bayer HealthCare US Funding LLC is a Delaware limited liability company whose members are Bayer AG, Bayer Pharmaceuticals AG, and Bayer World Investments B.V. *Id.* Bayer AG is a German corporation. *Id.* Bayer Pharmaceuticals AG is a German corporation. *Id.* Bayer World Investments B.V. is a private company with limited liability incorporated under the laws of the Netherlands and is wholly-owned by Bayer AG. *Id.*

34. The seventh member/owner of Bayer Healthcare LLC is "Coppertone LLC." *Id.* Coppertone LLC's principal place of business is in California. Coppertone LLC is a Delaware limited liability company. *Id.* The sole member/owner of Coppertone LLC is Bayer HealthCare US Funding LLC. *Id.* Bayer HealthCare US Funding LLC is a Delaware limited liability company whose members are Bayer AG, Bayer Pharmaceuticals AG, and Bayer World Investments B.V. *Id.* Bayer AG is a German corporation. *Id.* Bayer Pharmaceuticals AG is a German corporation. *Id.* Bayer World Investments B.V. is a private company with limited liability incorporated under the laws of the Netherlands and is wholly-owned by Bayer AG. *Id.*

35. The eighth member/owner of Bayer Healthcare LLC is MiraLAX LLC. *Id.* MiraLAX LLC is a Delaware limited liability company. *Id.* MiraLAX LLC's principal place of business is in California. The sole member/owner of MiraLAX LLC is Bayer HealthCare US Funding LLC. *Id.* Bayer HealthCare US Funding LLC is a Delaware limited liability company whose members are Bayer AG, Bayer Pharmaceuticals AG, and Bayer World Investments B.V. *Id.* Bayer AG is a German corporation. *Id.* Bayer Pharmaceuticals AG is a German corporation. *Id.* Bayer World Investments B.V. is a private company with limited liability incorporated under the laws of the Netherlands and is wholly-owned by Bayer AG. *Id.*

36. The Ninth member/owner of Bayer Healthcare LLC is "Bayer HealthCare US Funding LLC." *Id.* Bayer HealthCare US Funding LLC's principal place of business is in Pennsylvania. Bayer HealthCare US Funding LLC is a Delaware limited liability company whose members are Bayer AG, Bayer Pharmaceuticals AG, and Bayer World Investments B.V. *Id.* Bayer AG is a German corporation. *Id.* Bayer Pharmaceuticals AG is a German corporation. *Id.* Bayer World Investments B.V. is a private company with limited liability

incorporated under the laws of the Netherlands and is wholly-owned by Bayer AG. *Id*.

37. Accordingly, Bayer Healthcare LLC is a citizen of Delaware, New Jersey, Indiana, Pennsylvania and California for purposes of determining diversity under 28 U.S.C. § 1332. Therefore, no member or owner of Bayer Healthcare LLC is domiciled in the state of Florida and complete diversity exists with the Plaintiffs.

38. Defendant Bracco Diagnostics Inc. manufactures, tests, markets, advertises, and sells the linear GBCA named MultiHance.

39. Defendant Bracco Diagnostics, Inc. is a Delaware corporation with its principal place of business in New Jersey. Bracco Diagnostics, Inc. is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing MultiHance into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

40. Defendants GE Healthcare Inc. and General Electric Company manufacture, market, and sell Omniscan, a gadolinium-based contrast agent ("GBCA") that was injected into Plaintiff's body.

41. Defendant GE Healthcare Inc. is incorporated under the laws of the State of Delaware with its principal place of business in Boston, Massachusetts, where its headquarters are located and from where its officers direct, control, and coordinate the company's activities. GE Healthcare Inc. is thus a citizen of both the State of Delaware and the Commonwealth of Massachusetts. GE Healthcare Inc. is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Omniscan into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

42. Defendant General Electric Company is incorporated under the laws of the State of New York with its principal place of business in Boston, Massachusetts, where its headquarters are located and from where its officers direct, control, and coordinate the company's activities. General Electric Company is thus a citizen of both the State of New York and the Commonwealth of Massachusetts. General Electric Company is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing Omniscan into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

43. Defendant McKesson Corporation ("McKesson") distributes Magnevist, MultiHance, Omniscan, and other gadolinium-based contrast agents in New York. Plaintiff alleges that McKesson distributed the Magnevist, MultiHance, and Omniscan that was injected into Plaintiff.

44. Defendant McKesson Corporation is a Delaware corporation with its principal place of business in California. McKesson Corporation is duly authorized to conduct business in the State of New York and does significant business in the State of New York. McKesson is engaged in the business of storing, distributing, selling, marketing, and/or introducing Magnevist, MultiHance, and Omniscan into interstate commerce, either directly or indirectly through third parties or related entities. This court has personal jurisdiction over said Defendant under the doctrine of specific jurisdiction because said Defendant purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim arises out of Defendant's forum-related activities.

45. As used herein, "Defendants" includes Bayer HealthCare Pharmaceuticals Inc., Bayer Corporation, and Bayer Healthcare LLC, Bracco Diagnostics, Inc., GE Healthcare Inc., General Electric Company, and McKesson Corporation.

46. Defendants are authorized to do business in the Southern District of New York

and derive substantial income from doing business in this state.

47. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities with the Southern District of New York, thus invoking the benefits and protections of its laws.

48. Upon information and belief, Defendants did act together to design, sell, advertise, manufacture, promote and/or distribute Magnevist, MultiHance, and Omniscan with full knowledge of its dangerous and defective nature.

FACTS COMMON TO ALL CAUSES OF ACTION

49. The type of gadolinium retention sustained by Plaintiff occurs in patients without chronic/severe kidney disease or acute kidney injury who develop persistent symptoms that arise hours to months after the administration of a linear gadolinium-based contrast agent. Plaintiff had no preexisting disease or subsequently developed disease of an alternate known process to account for the symptoms. This is a progressive condition for which there is no known cure.

50. During the years that Defendants manufactured, marketed, distributed, sold, and administered linear gadolinium-based contrast agents, there have been numerous case reports, studies, assessments, papers, peer reviewed literature, and other clinical data that have described and/or demonstrated gadolinium retention in connection with the use of linear gadolinium-based contrast agents.

51. Defendants discovered newly acquired information after the FDA's initial approval of their drugs' labels regarding the risks and dangers of retention and physical injuries associated therefrom of linear gadolinium-based contrast agents. Defendants failed to warn Plaintiff and her healthcare providers about the serious health risks associated with linear gadolinium-based contrast agents, and failed to disclose the fact that there were safer alternatives (e.g., macrocyclic agents instead of linear agents). Therefore, it was reasonably foreseeable that that Defendants' drugs would cause gadolinium retention, fibrosis, and related injuries.

52. As a direct and proximate result of receiving injections of linear gadolinium-

based contrast agents manufactured, distributed, marketed, and/or sold by Defendants, Plaintiff developed gadolinium retention resulting in fibrosis in her organs, skin, and bones, retained gadolinium in her brain, and related injuries.

53. Had Plaintiff and/or her healthcare providers been warned about the risks associated with linear gadolinium-based contrast agents, she would not have been administered linear gadolinium-based contrast agents and would not have been afflicted with gadolinium retention resulting in fibrosis in her organs, skin, and bones, retained gadolinium in her brain, and related injuries.

54. As a direct and proximate result of Plaintiff being administered linear gadolinium-based contrast agents, she has suffered severe physical injury and pain and suffering, including, but not limited to, gadolinium retention resulting in fibrosis in her organs, skin, and bones, retained gadolinium in her brain, and related injuries.

55. As a direct and proximate result of being administered linear gadolinium-based contrast agents, Plaintiff suffered and continues to suffer significant mental anguish and emotional distress and will continue to suffer significant mental anguish and emotional distress in the future.

56. As a direct and proximate result of being administered linear gadolinium-based contrast agents, Plaintiff has also incurred medical expenses and other economic damages and will continue to incur such expenses in the future.

57. The nature of Plaintiff's injuries and damages, and their relationship to linear gadolinium-based contrast agents, were not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiff, until a time less than three years before the filing of her complaint. Prior to filing her complaint, Ms. Sabol took a urine test on April 8, 2016 that conclusively demonstrated the continued presence of toxic levels of gadolinium in her body.

58. Meanwhile, unbeknownst to Plaintiff, the manufacturers of the linear GBCAs have known since the 1980s that their drugs could cause retention of toxic gadolinium. But their

claims to the public and healthcare providers have been misleading and false.

59. In 1984 – prior to FDA approval – the inventors of linear gadolinium-based contrast agents claimed that their product, Gd-DTPA, did not cross the blood-brain barrier, and that the bonds between the toxic gadolinium and its protective coating did not break inside the body. Additionally, they claimed that there would be no toxic gadolinium residue left behind to cause illness.[1]

60. There are two basic types of contrast agents differentiated by their chemical structure – linear agents and macrocyclic agents. The main difference is that the linear agents do not fully surround the gadolinium ion, whereas the macrocyclic agents form a more complete ring around the gadolinium ion which creates a stronger bond. The linear agents include: Magnevist (manufactured by Bayer), Omniscan (manufactured by GE), OptiMark (manufactured by Guerbet/ Mallinckrodt/ Liebel-Flarsheim), and MultiHance (manufactured by Bracco).

61. Magnevist, a linear agent, was the first gadolinium-based contrast agent to reach the market after receiving FDA approval in 1988, and in that same year, it was recognized in a paper that gadolinium was breaking free from the bonds in the linear-based contrast agents and this was in part due to the competition for its protective layer (chelate) by other essential metals in the body such as zinc, copper, and iron.[2] Furthermore, emerging science showed that the bond between toxic gadolinium and its chelate or cage (Gd-DTPA) became very weak and separates easily in low pH conditions such as those found in many compartments of the human body including extracellular fluid spaces.

62. Stability differences among gadolinium contrast agents have long been recognized in laboratory (in vitro), and deposition of toxic gadolinium in tissues has been described in animal models since at least 1984. The first major study that showed deposition in

[1] Brasch RC. Inherent contrast in magnetic resonance imaging and the potential for contrast enhancement – the 1984 Henry Garland lecture. *West J Med.* 1985 Jun; 142:847-853.

[2] Huckle JE, Altun E, Jay M, et al. Gadolinium deposition in humans: when did we learn that gadolinium was deposited in vivo? *Invest. Radiol*. 2016; 51:236-240.

humans appeared in 1998 regarding patients with renal failure and later in 2004 in patients with normal renal function.[3]

63. Laboratory (in vitro) studies assessing the stability of each gadolinium-based contrast agent in human blood were performed and demonstrated that, over time, greater percentages of gadolinium were released from linear agents as compared to the macrocyclic agents.[4]

64. The lack of stability seen within the linear agents was dismissed as an issue by the Defendants claiming that the GBCA's were excreted out of the body according to the drug's claimed half-life, before the chelate could release the toxic gadolinium. However, it was later noted that some conditions could cause prolonged retention of the contrast agents, thus allowing more toxic gadolinium to be released in the bodies of patients. In addition, a delayed elimination phase of the gadolinium-based contrast agents would later be discovered.

65. Peer-reviewed articles on the deposition of gadolinium in animals with normal renal function, some illustrating deleterious consequences, have been published as early as 1984.[5]

66. Three months after the FDA approval of GE's Omniscan (a linear contrast agent) in 1993 the preclinical safety assessment and pharmacokinetic data were published describing its pharmacokinetics in rats, rabbits, and cynomolgus monkeys. These studies noted that while toxic gadolinium was no longer detectable in the blood 7-days after administration, quantifiable concentrations of gadolinium were persistent in both the renal cortex and areas around bone cartilage.[6]

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[3] *Id.*

[4] Tweedle MF, Eaton SM, Eckelman WC, et al. Comparative chemical structure and pharmacokinetics of MRI contrast agents. *Invest. Radiol.* 1988; 23 (suppl 1): S236-S239; *see also* Frenzel T, Lengsfeld P, Schimer H, et al. Stability of gadolinium-based magnetic resonance imaging contrast agents in serum at 37 degrees C. *Invest. Radiol.* 2008; 43:817-828.

[5] Weinman HJ, Brasch RC, Press WR, et al. Characteristics of gadolinium-DTPA complex: a potential NMR contrast agent. *AJR Am J Roentgenol*. 1984; 142: 619-624.

[6] Harpur ES, Worah D, Hals PA, et al. Preclinical safety assessment and pharmaco-kinetics of gadodiamide injection, a new magnetic resonance imaging contrast agent. *Invest Radiol.* 1993; 28 (suppl 1): S28-S43.

67. The first report of toxic gadolinium retention in humans may have been presented in September 1989, a little over 1 year after the approval of Magnevist. Authors *Tien et al.* reported that intracerebral masses "remained enhanced on MRI images obtained 8 days after injection of gadolinium DTPA dimeglumine (Magnevist)."[7] Subsequent chemical analysis revealed that a high concentration of gadolinium remained in the tissue.

68. Defendants knew that their linear GBCAs did not have very stable bonds and could come apart easily causing significant toxicity in humans. Defendants have known about the risks that linear gadolinium-based contrast agents pose to people with normal kidney function for years. Pharmacokinetic studies in 1991 indicated that gadolinium retention was occurring in people with normal renal function.[8]

69. In 2004, gadolinium was shown to be deposited in the resected femoral heads (bones) of people who had undergone gadolinium MRI studies.[9] Since then, studies have continued to indicate that gadolinium remains within people's bodies long after the suggested half-life.

70. Despite this well-documented evidence of gadolinium retention, Defendants have continuously failed to warn consumers and their healthcare providers on the label of their products, or anywhere that a patient or physician could be informed.

71. Dermatologists, nephrologists, and other scientists connected the administration of linear gadolinium-based contrast agents to a rapidly progressive, debilitating and often fatal condition called gadolinium-induced "Nephrogenic" Systemic Fibrosis (NSF), prompting the Food and Drug Administration (FDA) to issue a black box warning regarding the release of toxic gadolinium from the linear contrast agents, and its long-term retention in the bodies of

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[7] Tien RD, Brasch RC, Jackson DE, et al. Cerebral Erdheim-Chester disease: persistent enhancement with Gd-DTPA on MR images. *Radiology*. 1989; 172:791-792.
[8] Schumann-Giampieri G, Krestin G. Pharmacokinetics of Gd-DTPA in patients with chronic renal failure. *Invest Radiol.*, 1991; 26:975-979.
[9] Gibby WA, Gibby KA, Gibby WA. Comparison of Gd DTPA-BMA (Omniscan) versus Gd HP-DO3 (ProHance) retention in human bone tissue by inductively coupled plasma atomic emission spectroscopy. *Invest Radiol.*, 2004; 39:138-142.

animals and humans (for patients with abnormal kidney function) on all gadolinium-based contrast agents in 2007.

72. Defendants corrected their label to include contraindications for use in people with kidney disease and acute kidney injury.

73. There were over 500 NSF cases reported and estimated to be well over a thousand non-reported. There was a prior MDL and other litigation involving NSF against the defendants in the current litigation. A trial in that litigation resulted in a verdict in favor of the plaintiff and against GE. The litigation resolved and the MDL was formally closed in 2015. Due to the new black box warning in the GBCA's labelling, doctors stopped using GBCAs in patients with chronic/severe kidney disease or acute kidney injury. However, the warnings for patients with normal kidney function remained unchanged until May 21, 2018, and as a result the linear GBCAs continued to be widely used and marketed notwithstanding the Defendants' knowledge of the dangers of the product. This case and the others pending throughout the country involve widespread fibrosis and other symptoms in the bodies of patients with normal kidney function.

74. The vast majority of the medical community was not aware, until recently, of any disease that was associated with gadolinium other than NSF, which was defined as only occurring in patients with renal failure.

75. Gadolinium toxicity is, therefore, an underreported and underdiagnosed condition. Over the past several years (since the link between gadolinium-based contrast agents and NSF was acknowledged) patients with normal renal function have been forming advocacy groups and coming forward to create awareness for their condition. Symptomatic patients often have documentation of high levels of gadolinium in their blood and urine long after their exposure to gadolinium-based contrast agents. Many patients also have tissue biopsies of various parts of their body that show additional evidence of retained gadolinium years after their exposure.

76. Some patients sent several strongly worded letters with scientifically-supported

research data to the FDA, warning about the occurrence of gadolinium toxicity in those with normal renal function following injections of gadolinium-based contrast agents. Correspondence was confirmed as early as 2012.

77. In 2013, while examining non-contrast enhanced MRI images, Japanese researchers found evidence of retained gadolinium in the brains of patients with normal renal function that had previously received one or more injections of gadolinium-based contrast agents up to several years prior. They found that the brain had hyperintense signals in critical areas of the brain.[10]

78. These findings were confirmed by scientists at the Mayo Clinic in 2014 when autopsy studies were performed on 13 deceased individuals, all of whom had normal or near normal renal function and who had received six or more injections of gadolinium-based contrast agents in the years prior. Up to 56 mcg of gadolinium per gram of desecrated tissue were found within the brains of these patients.[11]

79. In July of 2015, in response to the Mayo Clinic study's findings, the FDA issued a new public safety alert stating that the FDA is evaluating the risk of brain deposits from repeated use of gadolinium-based contrast agents used in MRIs.

80. In September 2017, the FDA's medical advisory committee voted 13 to 1 in favor of adding a warning on labels that gadolinium can be retained in some organs, including the brain, even in patients with healthy kidneys.

81. In December 2017, the FDA required a new class warning and other safety measures for all gadolinium-based contrast agents for MRIs concerning gadolinium remaining in patients' bodies, including the brain, for months to years after receiving these drugs. The FDA required manufacturers to issue a patient medication guide, providing educational information

[10] Kanda T, Ishii K, Kawaguchi H, et al. High signal intensity in the dentate nucleus and globus pallidus on unenhanced T1-weighted MR images: relationship with increasing cumulative dose of a gadolinium-based contrast material. *Radiology*. 2014; 270: 834-841.

[11] McDonald RJ, McDonald JS, Kallmes DF, et al. Intracranial gadolinium deposition after contrast-enhanced MR imaging. *Radiology*. 2015; 275:772-782.

that every patient must be asked to read before receiving a GBCA. The FDA also required manufacturers of GBCAs to conduct human and animal studies to further assess their safety.

82. On May 21, 2018, the GBCA manufacturers finally issued a joint warning to patients with normal kidney function. This new "Important Drug Warning" issued by Bayer, GE, Bracco, and Guerbet included the following:

a. "Subject: Gadolinium from GBCAs may remain in the body for months to years after injection;"
b. A new class warning, patient counseling, and a medication guide;
c. Warning that gadolinium is retained for months to years in several organs;
d. Warning that the highest concentrations of retained gadolinium are found in bone, followed by organs (brain, skin, kidney, liver, and spleen);
e. Warning that the duration of gadolinium retention is longest in bone and varies by organ;
f. Warning that linear GBCAs cause more retention than macrocyclic GBCAs;
g. Warning about reports of pathological skin changes in patients with normal renal function;
h. Warning that adverse events involving multiple organ systems have been reported in patients with normal kidney function;
i. Warning that certain patients are at higher risk:
    i. patients with multiple lifetime doses;
    ii. pregnant patients;
    iii. pediatric patients;
    iv. patients with inflammatory process;
j. Instructions for health care providers to advise patients that:
    i. Gadolinium is retained for months or years in brain, bone, skin, and other organs in patients with normal renal function;
    ii. Retention is greater following administration of linear GBCAs than

following administration of macrocyclic GBCAs.

This also warning deliberately downplays the state of the evidence concerning the health effects of gadolinium retention.

83. Prior to May 21, 2018, Defendants failed to warn Plaintiff, her health care providers, and other patients and doctors throughout the United States about the specific concerns and warnings listed in the preceding paragraph.

84. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiff the nature of Plaintiff's injuries and the connection between her injuries and the Defendants' tortious conduct.

FIRST CAUSE OF ACTION
(Against All Defendants)
STRICT PRODUCT LIABILITY: FAILURE TO WARN

85. Plaintiff incorporates by reference and realleges each paragraph set forth above.

86. Defendants' linear gadolinium-based contrast agents were defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing.

87. Magnevist, MultiHance, and Omniscan were defective at the time of their manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying Magnevist, MultiHance, and Omniscan failed to warn of the dangerous risks posed by Magnevist, MultiHance, and Omniscan, including the risk of gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain.

88. At all times alleged herein, Magnevist, MultiHance, and Omniscan were defective and Defendants knew that Magnevist, MultiHance, and Omniscan were to be used by consumers without inspection for defects. Moreover, Plaintiff, her prescribing physicians, and her health care providers neither knew nor had reason to know at the time of Plaintiff's use of Magnevist, MultiHance, and Omniscan of the aforementioned defects. Ordinary consumers

would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.

89. At all times alleged herein, Magnevist, MultiHance, and Omniscan were prescribed to and used by Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants.

90. The designs of Magnevist, MultiHance, and Omniscan were defective in that the risks associated with using Magnevist, MultiHance, and Omniscan outweighed any benefits of the design. Any benefits associated with the use of Magnevist, MultiHance, and Omniscan were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results.

91. The defect in design existed when the product left Defendants' possession.

92. At the time Magnevist, MultiHance, and Omniscan left the control of Defendants, Defendants knew or should have known of the risks associated with use of Magnevist, MultiHance, and Omniscan.

93. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Magnevist, MultiHance, and Omniscan, and through that conduct have knowingly and intentionally placed Magnevist, MultiHance, and Omniscan into the stream of commerce with full knowledge that they reach consumers such as Plaintiff who received it.

94. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Magnevist, MultiHance, and Omniscan to Plaintiff and to her prescribing physicians. Additionally, Defendants expected the Magnevist, MultiHance, and Omniscan that they were selling, distributing, supplying, manufacturing, and/or promoting to reach – and Magnevist, MultiHance, and Omniscan did in fact reach – prescribing physicians and consumers, including Plaintiff and her prescribing physicians, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

95. At all times herein mentioned, the aforesaid product was defective and unsafe

in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants and ingested by Plaintiff. The defective condition of Magnevist, MultiHance, and Omniscan was due in part to the fact that they were not accompanied by proper warnings regarding the possible side effect of developing long-term and irreversible gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposits in the neuronal nuclei of the brain, as a result of its use.

96. This defect caused serious injury to Plaintiff, who used Magnevist, MultiHance, and Omniscan in their intended and foreseeable manner.

97. At all times herein mentioned, Defendants had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that the product did not cause users to suffer from unreasonable and dangerous side effects.

98. Defendants so negligently and recklessly labeled, distributed, and promoted the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended.

99. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with Magnevist, MultiHance, and Omniscan.

100. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that Magnevist, MultiHance, and Omniscan cause serious injuries, they failed to exercise reasonable care to warn of the dangerous side effect of developing irreversible gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain, from Magnevist, MultiHance, and Omniscan use, even though this side effect was known or reasonably scientifically knowable at the time of distribution. Defendants willfully and deliberately failed to avoid the consequences associated with their failure to warn, and in doing

so, Defendants acted with a conscious disregard for the safety of Plaintiff.

101. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

102. Defendants, as the manufacturers and/or distributors of the subject product, are held to the level of knowledge of an expert in the field.

103. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

104. Had Defendants properly disclosed the risks associated with Magnevist, MultiHance, and Omniscan, Plaintiff would have avoided the risk of gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain, by not using Magnevist, MultiHance, and Omniscan.

105. As a direct and proximate result of the carelessness, negligence, recklessness, and gross negligence of Defendants alleged herein, and in such other ways to be later shown, the subject product caused Plaintiff to sustain injuries as herein alleged.

106. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent, and were done with a conscious disregard for the health, safety and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such, Plaintiff is entitled to exemplary or punitive damages.

107. WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

SECOND CAUSE OF ACTION
(Against All Defendants)
NEGLIGENCE

108. Plaintiff incorporates by reference and realleges each paragraph set forth above.

109. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Magnevist, MultiHance, and Omniscan.

110. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

111. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants, including, but not limited to, one or more of the following particulars:

a) In the design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of Magnevist, MultiHance, and Omniscan;

b) In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of Magnevist, MultiHance, and Omniscan's dangerous and defective characteristics;

c) In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for the subject product;

d) In promoting the subject product in an overly aggressive, deceitful, and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause irreversible gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain;

e) In representing that the subject product was safe for its intended use when, in fact, the product was unsafe for its intended use;

f) In failing to perform appropriate pre-market testing of the subject product;

g) In failing to perform appropriate post-market surveillance of the subject product;

h) In failing to adequately and properly test Magnevist, MultiHance, and Omniscan before and after placing them on the market;

i) In failing to conduct sufficient testing on Magnevist, MultiHance, and Omniscan which, if properly performed, would have shown that Magnevist, MultiHance, and Omniscan had the serious side effect of causing gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain;

j) In failing to adequately warn Plaintiff and her healthcare providers that the use of Magnevist, MultiHance, and Omniscan carried a risk of developing irreversible gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain;

k) In failing to provide adequate post-marketing warnings or instructions after Defendant knew or should have known of the significant risk of gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain, associated with the use of Magnevist, MultiHance, and Omniscan; and

l) In failing to adequately and timely inform Plaintiff and the healthcare

industry of the risk of serious personal injury, namely irreversible gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain, from Magnevist, MultiHance, and Omniscan use as described herein.

112. Defendants knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.

113. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, gadolinium retention in multiple organs (brain, heart, liver, kidney, bones, and skin), the resulting fibrosis in organs, bone, and skin, and its tendency to cross the blood-brain barrier and deposit in the neuronal nuclei of the brain. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

114. WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

(a) For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;

(b) For medical, incidental, and hospital expenses according to proof;

(c) For pre-judgment and post-judgment interest as provided by law;

(d) For compensatory damages in excess of the jurisdictional minimum of

this Court;

(e) For consequential damages in excess of the jurisdictional minimum of this Court;

(f) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;

(g) For attorneys' fees, expenses, and costs of this action; and

(h) For such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

In addition to the above, Plaintiff hereby demands a trial by jury for all causes of action and issues that can be tried by a jury.

Dated this 30th day of November, 2018

Respectfully submitted,
By: */s/ Daniel C. Burke*

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CERTIFICATE OF SERVICE

I, Daniel C. Burke, hereby certify that on November 30, 2018, a copy of this Complaint was filed electronically. Notice of this filing will be sent to all parties by operation of this Court's CM/ECF.

/s/ Daniel C. Burke